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Applicability of Requirements to Manufacturers of Industrial Dielectric Heaters, Including Radiofrequency (RF) Sealers, and Electromagnetic (EM) Induction Heating Equipment

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1002

[Docket No. 79N-0260]

Records and Reports; Applicability of Requirements to Manufacturers of Industrial Dielectric Heaters, Including Radiofrequency (RF) Sealers, and Electromagnetic (EM) Induction Heating Equipment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adding industrial dielectric heaters, including radiofrequency (RF) sealers, and electromagnetic (EM) induction heating equipment to the listing of electronic products for which manufacturers are required to submit initial reports, annual reports, and model change reports. The amendment also requires manufacturers to maintain, preserve, and allow inspection of certain records on these sealer and heater products.

EFFECTIVE DATE: August 14, 1980.

FOR FURTHER INFORMATION CONTACT: Richard S. Sternchak, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 1979 (44 FR 49699), FDA proposed to amend § 1002.61 (21 CFR 1002.61) by adding a new paragraph (c)(5) which would list all RF sealers and EM induction heating equipment operating in the 10-megahertz (MHz) to 300-MHz frequency range in the specific product group for which manufacturers are required to submit initial reports under § 1002.10 (21 CFR 1002.10), annual reports under § 1002.11 (21 CFR 1002.11), and model change reports under § 1002.12 (21 CFR 1002.12). In addition, the amendment proposed that manufacturers be required to maintain certain records under § 1002.30 (21 CFR 1002.30) and to comply with the preservation and inspection of records provisions of § 1002.31 (21 CFR 1002.31). Interested persons were given until October 23, 1979, to file written comments with the Hearing Clerk, FDA, regarding the proposal.

The agency received nine comments on the proposal—three from labor organizations, two from product users, two from trade associations, one from a Federal governmental agency, and one from a public interest group. Four comments were in full support of the effort of the agency of gather information. Two of these comments further encouraged the agency to proceed with the promulgation of a radiation safety performance standard for RF sealers and heaters. Three comments disagreed with the proposed rule for reporting and recordkeeping, primarily on the ground that the action would impose a high economic impact on the RF dielectric heater, sealer, and EM induction heating equipment industry without sufficient proof that these products present a significant health hazard to humans. Two comments expressed no direct opinion with regard to the proposed action of the agency. However, one requested information on the economic impact of the proposed rule on small businesses in the industry, and another recommended a clarification to particular manufacturers who may be uncertain as to their reporting responsibilities.

The following is a summary of the comments received and the agency's responses to them:

1. One comment expressed full endorsement based on "urgent need." Another favored the proposed action on the basis that workers may suffer from possible RF radiation exposure. A third expressed alarm at the recent reports of adverse health effects from exposure to low-level RF radiation. A fourth comment said the proposed action was "gratifying."

These comments support FDA's contention that currently marketed RF dielectric and EM induction heating equipment may present a health hazard to persons exposed to the stray RF energy. Information is now needed on the design and emission characteristics of these sealers and heaters to help FDA's Bureau of Radiological Health ("the Bureau") evaluate the need for promulgating a radiation safety performance standard for the products.

2. Three comments argued that the agency's proposed action was not appropriate because the biological basis was not substantial enough to consider these products to be potential health hazards. One comment questioned what evidence there was for FDA's "assumption" that RF sealing machnes may present a health hazard, and asked how many, if any, persons have experienced health problems as a result of RF exposure from these machines. Another comment asserted that documentation fails to show that any dangers exist from these type products. The third comment argued that the "paucity of data" concerning the effects on humans of nonionizing RF radiation is a positive indication that very little danger actually exists from ISM (industrial, scientific, and medical) equipment. The same comment indicated that no harmful results have occurred from exposure to fields in this frequency range; that exposure to EM radiation is incidential and unintentional; and that because of good design and adequate shielding, dielectric and induction heaters do not emit significant levels of unnecessary radiation.

The agency disagrees with these statements because of the documentation it has on record. Field measurements and other data obtained by various State and Federal agencies in independent field surveys (Refs. 1 and 2) clearly substantiate that RF dielectric heaters, sealers, and EM induction heaters being used in industry today commonly emit stray RF radiation far in excess of the generally accepted recommended RF radiation protection guidelines set by the American National Standards Institute, Inc., (ANSI-C95.1, 1974), for the frequency range between 10 MHz and 100 GHz (gigahertz) (Ref. 3). Stray RF radiation is considered unnecessary because it does not contribute to the intended function of the product, and it can be eliminated or reduced significantly by using properly installed and grounded shielding. While the agency agrees that stray radiation is incidential to the function of the product, and may be unintentional, the radiation is considered uncontrolled because adequate shielding is rarely employed or is removed in the field. An informational survey conducted by the agency determined that approximately 67 percent of those companies now manufacturing RF sealers and EM induction heating equipment claimed to offer some form of shielding as an option (Ref. 4). Manufacturers, however, generally do not recommend it, and few purchasers specify the option because shielding increases the base price of the unit and allegedly decreases production because of operator-machine interface problems when incorporated. Equipment manufactured in the United States for sale in certain European countries is shielded because these countries impose stricter controls on RF emission.

The survey also determined that approximately one-third of the companies queried acknowledged that they had received compliants about possible health hazards from operators of this type of machine. However, the companies claimed that, upon investigation, the allegations proved unfounded. The agency does not have

an exact accounting of the number of persons having experienced health problems from these products, but the number of injury claims has increased considerably over the last year. Reports on record with the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) indicate that workers are being heated and are complaining of other bioeffects. A primary FDA concern is the ability of the RF radiation to cause deep body heating and localized rises in tissue temperature that may result in injury or death of certain body cells without the awareness of the person being exposed.

Some experiments conducted by various institutional groups in several countries have shown biological effects in laboratory animals exposed to RF radiation at certain frequencies and at relatively low-energy levels (Refs. 5, 6, 7, and 8). Recent reports have indicated that the biological effects observed in average size laboratory animals caused by energy absorptions associated with low-to-moderate exposures at certain RF frequencies can be correlated to a grounded human under different conditions of exposure and may occur in humans at exposure levels even lower than those reported for the animals (Refs. 6, 9, 10, 11, and 12). The validity of extrapolation of experimental animal data to humans, however, has been questioned. While it is recognized that the existing bioeffects data base is incomplete and that scientists are not in complete agreement on the interpretation of available data, the agency believes that there is sufficient evidence of these effects to cause concern about human exposure, and, therefore, to justify this rule.

3. The same three comments argued against the agency's action on economic grounds. One comment said that this action will increase the cost of the equipment, impair productivity, and further increase the cost of manufacture. Another comment asserted that the effect of the reporting and recordkeeping requirements will mean keeping a voluminous set of records, and will have a substantial cost impact on the industry. The third comment questioned the agency's assertion that no major economic consequences will result from the proposed rule.

In accordance with Executive Order 12044, the economic effects of the proposed rule have been carefully analyzed in a regulatory analysis assessment, and it has been determined that the rulemaking does not involve major economic consequences as defined by that order.

Records that manufacturers would be required to maintain and preserve include standard sales, work, and shipping order documentation and other information ordinarily generated and maintained by manufacturers as the result of proper quality control and testing procedures during manufacturing. If done properly, initial reporting is a one-time effort. Supplementary and model change reports include only those changes in the information originally submitted in the initial report and are necessarily shorter documents. Annual reports summarize the contents of the records required to be maintained and reflect only the production activities and those changes in information originally supplied during the previous year. The agency believes that the scope of these requirements will not result in either voluminous recordkeeping or unduly burdensome reporting, even for small businesses.

4. In a series of questions, one of the comments asked what economic impact the proposed rule would have on small businesses. The comment also asked if the proposed rule makes any distinctions based on size of the firms, and if the proposed rule would increase the cost of starting a new business in this field.

Surveys have indicated that all companies in the RF dielectric and EM induction heater industry are relatively small (Ref. 4). The agency believes that the cost in terms of money and time for a manufacturer to satisfy the requirements imposed by this rule is related more to a company's efficiency of operation and to the number of different product models it manufactures than to its size measured by the number of people it employs or the volume of business it conducts. The small economic impact of this rule will be the same for a company just starting business as it will be for a company already in the business. The agency believes that the need for the action, considering public safety, justifies the small cost it may impose. Also, manufacturers of these electronic products may request special exemptions from reporting and recordkeeping requirements if they can satisfy the provisions of § 1002.50 (21 CFR 1002.50).

5. One comment suggested that repetitious reporting could be avoided if all Federal agencies having a common interest in high-frequency heaters would cooperate in sharing one report submitted by each manufacturer.

The agency acknowledges that a "one-report" system would be ideal. However, it is impossible because FDA knows of no other agency that is requesting the same type of safety and health-related information.

6. Two comments expressed concern that this action would lead to overregulation of the high frequency heating industry. One comment stated that this action will be another in a long series of governmental regulations and will lead to similar controls and reports by all users of these RF heat-sealing machines. The second comment stated that overly restrictive regulations might do more damage to American industry.

The agency emphasizes that requiring recordkeeping by, and reports from, manufacturers of industrial RF dielectric and EM induction heating equipment does not necessarily mean that the agency now intends to issue a radiation safety performance standard for these products. The review of all product information and bioeffects data being solicited and received may instead result in FDA's encouraging the private sector to establish a voluntary safety guideline, or even taking no further action. All available hazard information that is documented in scientific literature will be used as a basis for any proposed rulemaking. While the agency has no intention of compromising the health and safety of the general public, it also has no intention of issuing regulations if it determines that there is no clear need for doing so. The agency also stresses that this rule is intended only for manufacturers of these heater products and is not addressed to users of these products.

7. One comment suggested that the words "dielectric heaters" be used better to describe the industrial product group with which this rule is concerned because the term is "more descriptive and really generic."

The agency has reviewed the terminology used in the industry to describe these products and has found that they are called by a variety of names, depending on the method by which they produce the radiation or the application for which they are used. One reference stated that devices classified broadly as RF sealers, heaters, and gluers are also known (especially in the trade) as heat sealers, fusers, molders, fasteners, or embossers; high frequency (HF) sealers or dryers; electronic or electromagnetic sealers or welders; and dielectric heaters or flow molders. Another class of EM radiation-emitting devices includes "induction heaters" (Ref. 13). A second document referred to these products as "RF dielectric heaters (commonly known as RF sealers and heaters)" (Ref. 10). A third report indicated that there may be two distinct segments of industry which use RF

heating equipment (Ref. 4). The "thermoplastic" industry uses RF sealers to seal or emboss, while the "thermoset" industry uses RF equipment or heaters.

FDA has no objection to the use of the more general term suggested by the comment. In addition, this rule is intended to include RF dielectric and EM induction heating equipment used only for industrial purposes. Accordingly, the listing of these products in this final rule has been amended to include the words "Industrial dielectric heaters."

8. The same comment questioned the agency's action to extend the range of frequencies to cover all dielectric and induction heater products.

The agency intended that the proposed rule include all industrial RF and EM heating equipment that is used for the purpose of controllably heating dielectric materials. While many of the heaters and sealers operate in the three ISM frequency bands centered at 13.56 MHz, 27.12 MHz, and 40.68 MHz, the agency has recently learned that a few woodgluing machines operate at frequencies as low as 2 to 6 MHz, and a few RF heaters used for plastics operate at frequencies as high as 500 MHz (Refs. 8 and 10). Therefore, the agency is extending the frequency range of concern from 10 to 300 MHz to 2 to 500 MHz.

9. Another comment asked whether there was any correlation between RF sealers and transformers that contain the class of chemicals termed PCB's (polychlorinated biphenyls).

This rule includes all products used in industry where RF fields are the mechanism of energy transfer in such processes as sealing, dielectric welding, fastening, fusing, molding, embossing, drying or gluing materials including but not limited to plastics, wood, paper, rubber, textiles, and fibers. Transformers that contain PCB's are not products which perform these functions. Therefore, the agency does not consider these transformers subject to the requirement of this rule.

10. One comment said that no reliable monitoring equipment is presently commercially available to measure electric and magnetic field strengths in the near field in the frequency range defined in the proposed rule.

The agency advises that a recent NIOSH/OSHA bulletin lists (without endorsement) manufacturers of instruments for the measurement of radiofrequency energy in the near field (Ref. 8). Also, during the "Open Workshop on RF Sealers, Heaters, and Gluers" cosponsored by the FDA and OSHA on September 12–13, 1979, several instrument manufacturers in attendance stated interest in developing this type of instrumentation (Ref. 14).

11. One comment sought clarification as to which manufacturers of industrial RF dielectric and EM induction heaters need file the reports required for listed products in this rule. The comment stated that §§ 1002.10 and 1002.12 of the regulations specify that manufacturers are to file reports on listed products prior to the introduction of such products into commerce. It questioned whether a company that builds RF dielectric heaters or sealers solely for its own use and does not sell them to others would be deemed to have introduced these products into commerce. It argued that such a company would not be required to file reports on the devices.

The question raised is difficult to answer directly because of the complex set of qualifying circumstances that should be considered before a decision could be made. Generally speaking, an electronic product that is designed by a particular company and assembled by that company's personnel for sole use by that company in its manufacturing process is not subject to regulations issued under the Radiation Control for Health and Safety Act of 1968. This position is based on the assumptions: (1) That the product is not made on a continuing basis; (2) that it is not shipped out of the plant where produced; (3) that it is not sold to another party; and (4) that the company employing the device receives no direct compensation for its use. The product must be designed, assembled, and used by the same party in order that the product not be subject to regulation. The agency points out that there are other State and Federal agencies whose statutory responsibilities specifically deal with potential health hazards in the workplace, independent of the source of the equipment being operated (Ref. 15).

12. On its own initiative, the agency is revising § 1002.61(c)(3) because the listing of microwave ovens is already covered by § 1002.61(c)(1). The listing of industrial RF dielectric and EM induction heaters will be placed in § 1002.61(c)(3) rather than § 1002.61(c)(5) as proposed.

References

The following references, including pertinent background data and information supporting the agency's action, are on file in the office of the FDA Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and are available for public review:

1. Items 2–8: "Documentation Index for RF Sealers/EM Induction Heater Proposed Record and Reporting Requirements," filed with the Hearing Clerk's Office, FDA, under Docket No. 79N–0260, for proposed rule published in the **Federal Register**, August 24, 1979.

2. Conover, D. L., W. H. Parr, E. L. Sensintaffer, and W. E. Murray, Jr., "Measurement of Electric and Magnetic Field Strengths From Industrial Radiofrequency (15–40.68 MHz) Power Sources," *in* "Biological Effects of Electromagnetic Waves: Selected Papers of the USNC/URSI Annual Meeting (Boulder, CO., October 20–23, 1975). C. C. Johnson and M. L. Shore, eds., Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, DHEW Publication (FDA) No. 77–8011, 2:356–362 (1976).

3. American National Standards Institute, "Safety Level of Electromagnetic Radiation with Respect to Personnel," Report ANSI–C95.1 November 15, 1974.

4. Nesmith, B., "Informational Survey of Industrial RF Plastic Sealers and Induction Heating Equipment," DHEW, PHS, FDA, BRH, June 27, 1979.

5. "Biological Effects and Health Hazards of Microwave Radiation" Proceedings of an International Symposium, Warsaw, October 15–18, 1973, Polish Medical Publishers, Poland 1974.

6. "Interim Statement on RF Sealers," prepared by the Radiofrequency and Microwave Committee of the Interagency Regulatory Liaison Group, draft, March 16, 1979.

7. Glaser, Z. R. and C. H. Dodge, "Biomedical Aspects of Radiofrequency and Microwave Radiation: A Review of Selected Soviet, East European, and Western References," *in* Biological Effects of Electromagnetic Waves: Selected Papers of the USNC/URSI Annual Meeting (Boulder Co., October 20–23, 1975), C. C. Johnson and M. L. Shore, eds., Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, DHEW Publication (FDA) No. 77–8010, 1:2–34, (1976).

8. West, D., Z. Glaser, A. Thomas, V. Alexander, D. Conover, W. Murray, R. Curtis, S. Mallinger, A. Robins, and E. Bingham, "Radiofrequency (RF) Sealers and Heaters: Potential Hazards and Their Prevention," NIOSH/OSHA Current Intelligence Bulletin #33, December 4, 1979, and published in *the American Industrial Hygiene Association Journal*, 41(3):A–22 through A–38.

9. "NIOSH RF/Microwave Criteria Document," Final Director's Draft, February 29, 1980.

10. IRLG Radiofrequency and Microwave Committee: "Statement on Health and Safety Aspects of Working with RF Dielectric Heaters," Mod. 4th Draft, January 26, 1980.

11. "Thoughts About the Adequacy of Thermally Related Radiofrequency Exposure Safety Standards," prepared by R. A. Tell, U.S. Environmental Protection Agency, and F. Harlan, U.K. National Radiological Protection Board, November 1978.

12. Durney, C. H., et al., "Radiofrequency Radiation Dosimetry Handbook" (Second

Edition), Technical Report SAM–TR–78–22, prepared for USAF School of Aerospace Medicine, Brooks Air Force Base, Texas 78235, 1978.

13. Glaser, Z. R., "Introduction, Brief Background, and Some Uses of Radiofrequency (RF) Sealers, Heaters, and Gluers," presented at the Workshop on RF Sealers, Heaters, and Gluers, jointly sponsored by BRH and OSHA (Washington, DC, September 12–13, 1979).

14. "Open Workshop on RF Sealers, Heaters, and Gluers," (FDA) Docket No. 79N–0314, cosponsored by FDA and OSHA (Washington, DC, September 12–13, 1979). Proceedings of meeting in preparation.

15. U.S. Department of Labor, Occupational Safety and Health Administration: "OSHA Safety and Health Standards, 29 CFR 1910.97," OSHA 2206, Revised, November 7, 1978, Washington, DC.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 360A, 82 Stat. 1182–1184 (42 U.S.C. 263i)) and under authority delegate to the Commissioner of Food and Drugs (21 CFR 5.1), 21 CFR Part 1002 is amended in § 1002.61 by revising paragraph (c)(3), to read as follows:

§ 1002.61 List of specific product groups.

* * * * *

(c) * * *

(3) Industrial dielectric heaters, including radiofrequency (RF) sealers, and electromagnetic (EM) induction heating equipment that operate in the frequency range from 2 megahertz to 500 megahertz.

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Effective date. This regulation shall be effective August 14, 1980.

(Sec. 360A, 82 Stat. 1182–1184 (42 U.S.C. 263i))

Dated: June 26, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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